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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/961,083	10/30/97	CHOI	G PB340P2

022195  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
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HM12/0303

EXAMINER

HINES, J

ART UNIT	PAPER NUMBER
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1641

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DATE MAILED: 03/03/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/961,083

Applicant(s)

Choi, et al

Examiner

Ja-Na Hines

Group Art Unit

1641



☒ Responsive to communication(s) filed on Jan 13, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-197 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-197 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Based upon the applicants response to the election/restriction request of October 26, 1998, the restriction is further modified. The election of ten SEQ ID NO set forth in 1192 O.G. 68 (Nov. 19, 1996) assumed the DNA claimed was not known to express a known or functional protein. Based on applicants response, this is obviously not the case, therefore the instant application does not meet the requirements set forth in 1192 O.G. 68 (Nov. 19, 1996). The Examiner apologizes for the error and any inconveniences it may have caused.

Accordingly, each of the polynucleotide sequences and corresponding DNA sequences represent patentably distinct and independent invention, in that each DNA sequence is unrelated in structure and function and operation.

#### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. The Super Group of claims 22-197 are drawn to an isolated polynucleotide, classified in class 424, subclass 185.1.  
  
The Sub-Groups are as follows:
    - Ia. Claims 23-24, 53, 106 and 124 are drawn to an isolated polynucleotide, SEQ ID NO: 42, classified in class 424, subclass 185.1.

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- Ib. Claims 25-26, 54, 107 and 125 are drawn to an isolated polynucleotide, SEQ ID NO: 56, classified in class 424, subclass 185.1.
- Ic. Claims 27-28 and 78-91 are drawn to an isolated polynucleotide, SEQ ID NO: 66, classified in class 424, subclass 185.1.
- Id. Claims 29-30, 55, 72, 108 and 126 are drawn to an isolated polynucleotide, SEQ ID NO: 68, classified in class 424, subclass 185.1.
- Ie. Claims 31-32, 56, 73, 109 and 127 are drawn to an isolated polynucleotide, SEQ ID NO: 140, classified in class 424, subclass 185.1.
- If. Claims 33-34 and 92-104 are drawn to an isolated polynucleotide, SEQ ID NO: 158, classified in class 424, subclass 185.1.
- Ig. Claims 35-36, 57, 74, 110 and 128 are drawn to an isolated polynucleotide, SEQ ID NO: 178, classified in class 424, subclass 185.1.
- Ih. Claims 37-38, 58, 75, 111 and 129 are drawn to an isolated polynucleotide, SEQ ID NO: 218, classified in class 424, subclass 185.1.
- Ii. Claims 39-40, 59, 76, 112 and 130 are drawn to an isolated polynucleotide, SEQ ID NO: 220, classified in class 424, subclass 185.1.
- Ij. Claims 41-42, 60, 77, 113 and 131 are drawn to an isolated polynucleotide, SEQ ID NO: 222, classified in class 424, subclass 185.1.
- Ik. Claims 142, 161 and 180 are drawn to an isolated polynucleotide, SEQ ID NO: 41, classified in class 424, subclass 185.1.

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II. Claims 143, 162 and 181 are drawn to an isolated polynucleotide, SEQ ID NO: 55, classified in class 424, subclass 185.1.

Im. Claims 144, 163 and 182 are drawn to an isolated polynucleotide, SEQ ID NO: 67, classified in class 424, subclass 185.1.

In. Claims 145, 164 and 184 are drawn to an isolated polynucleotide, SEQ ID NO: 139, classified in class 424, subclass 185.1.

Io. Claims 146, 165 and 184 are drawn to an isolated polynucleotide, SEQ ID NO: 177, classified in class 424, subclass 185.1.

Ip. Claims 147, 166 and 185 are drawn to an isolated polynucleotide, SEQ ID NO: 217, classified in class 424, subclass 185.1.

Iq. Claims 148, 167 and 186 are drawn to an isolated polynucleotide, SEQ ID NO: 219, classified in class 424, subclass 185.1.

Ir. Claims 149, 168 and 187 are drawn to an isolated polynucleotide, SEQ ID NO: 221, classified in class 424, subclass 185.1.

Claims 22, 43-51, 52, 61-69, 105, 114-122, 123, 132-140, 141, 151-159, 160, 170-178, 179 and 189-197 are generic claims and will be evaluated with the appropriate subgroup election.

II. Claim 10 is drawn to a polypeptide, a polypeptide antigen, a vaccine and a kit for detecting *Streptococcus* classified in class 424, subclass 184.1.

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- III. Claim 14 is drawn to an antibody and a hybridoma which produces the antibody, classified in class 424, subclass 141.1.
- IV. Claim 17 is drawn to a method of preventing infection, classified in class 424, subclass 900.
- V. Claim 18 is drawn to a method of detecting *Streptococcus* under conditions such that hybridization occurs and a method of detecting *Streptococcus* using polymerase chain reaction, classified in class 424, subclass 9.1.
- VI. Claim 21 is drawn to a method of detecting *Streptococcus* using antibody-antigen complexes, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions in group I and II-VI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).
- 3. Inventions in groups I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the individual groups each disclose a different use for the products claimed.
- 4. Inventions in groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are claimed in groups II and III. There are different modes of operation function and effects since group II makes a polypeptide, an antigen, a vaccine and a kit used for detection while group III makes an antibody and a hybridoma cell.

5. Inventions in group IV and groups I-III and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group IV claims a method of prevention while the other groups do not disclose similar inventions .

6. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in group V are drawn to a materially different method of detection then group VI.

7. Because these inventions are distinct for the reasons given above and the search required for any one of the twelve groups is not required for any of the other groups, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Claims within groups II, III, IV and VI are to a plurality of disclosed patentably distinct products comprising materially different proteins. Should the inventions of groups II, III, IV or VI be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. In addition to the preceding restriction requirement, upon election of Super Group I the following additional election from the sub-groups, Ia-Ir, would be required: an election of the a DNA species for the polynucleotide, the heterologous polynucleotide sequence, the encoded polypeptide, the method for making a recombinant vector comprising the isolated polynucleotide,



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the recombinant vector, the polynucleotide associated with a heterologous regulatory sequence, the recombinant host cell and the method for producing the polypeptide.

An example for a election for a subgroup follows.

Group Ia. Claims 23-24, 53, 106 and 124 are drawn to an isolated polynucleotide, SEQ ID NO: 42, further, the generic claims 22, 43-52, 61-69, 105, 114-123 and 132-140 with respect to SEQ ID NO: 42 would be elected.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Friday from 6:30am to 4:00pm except for the second Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Application/Control Number: 08/961,083

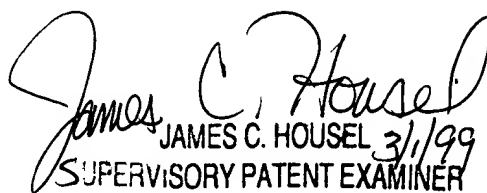
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

February 16, 1999

  
JAMES C. HOUSEL 3/1/99  
SUPERVISORY PATENT EXAMINER